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FDA Shrugs Off Concerns About Premature Births, Approves Pfizer RSV Vaccine for Pregnant Women

The U.S. Food and Drug Administration on Monday approved Pfizer's Abrysvo vaccine, a maternal vaccine meant to protect infants against respiratory syncytial virus, or RSV, through 6 months of age — despite safety concerns, including from the FDA's own advisers.

By **Brenda Baletti, Ph.D.**

23

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The U.S. Food and Drug Administration (FDA) on Monday approved Pfizer's Abrysvo vaccine, a maternal vaccine meant to protect infants against respiratory syncytial virus, or RSV, through 6 months of age.

The agency approved the vaccine despite concerns raised by members of the FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) about premature births identified during Pfizer's clinical trials.

VRBPAC panelist Dr. Paul Offit, a pediatrician at Children's Hospital of Philadelphia and a frequently cited vaccine advocate, said he doesn't believe there is enough data to indicate the safety of the vaccine is "reassuring."

In its statement to investors, however, Pfizer was enthusiastic about the prospect of the vaccine.

"ABRYSVO's approval as the first and only maternal immunization to help protect newborns immediately at birth through six months from RSV marks a significant milestone for the scientific community and for public health," said Annaliesa Anderson, Ph.D., Pfizer's senior vice president and chief scientific officer, Vaccine Research and Development.

RFK Jr./Hooker NEW book: Vax-Unvax. Order Now!

RSV generally causes only mild, cold-like symptoms in infants and young children, most of whom get the illness by age 2 and typically don't require medical attention. The Centers for Disease Control and Prevention (CDC) estimates 58,0000-80,0000 children younger than age 5 are hospitalized and 100-300 children die from RSV overall in any given year.

Commenting on the vaccine after VRBPAC endorsed it in May, Dr. Peter McCullough told The Defender:

> "This product represents an unprecedented attempt to vaccinate mothers for no benefit to them and only theoretical efficacy in babies. In the trial, less than 2% of infants at any time point contracted RSV, which is easily treatable with nebulizers."

Before the drug can be prescribed to pregnant women, the CDC's Advisory Committee on Immunization Practices (ACIP) must recommend the vaccine and CDC Director Mandy Cohen must accept the recommendation. She is widely expected to do so, STAT News reported.

The next ACIP meeting is scheduled for October, but STAT said a special meeting might be called in the coming days, given "last year's early start to the RSV season."

Earlier this month, the CDC recommended the first-ever monoclonal antibody — Sanofi and AstraZeneca's Beyfortus — to protect all newborns against RSV after the FDA approved the drug.

It made that recommendation despite 12 infant deaths during the clinical trials and criticism from medical experts who said the move was unnecessary and not worth the known risks.

In late May, the FDA approved the same Pfizer Abrysvo vaccine approved Monday for pregnant women for use in adults over 60.

And earlier in May the agency approved GSK's Arexvy, the first vaccine authorized for RSV, for adults over 60.

20% higher rate of premature birth among vaccinated mothers in clinical trials

According to the FDA, Abrysvo will be administered to pregnant women between 32 and 36 weeks of pregnancy as a single-dose injection into the muscle.

It said the "safety and effectiveness" of the shots were determined through "ongoing, randomized, placebo-controlled international clinical studies."

Pfizer reported that in its Phase 3 clinical trial — MATISSE (MATernal Immunization Study for Safety and Efficacy), published in the New England Journal of Medicine — the shot was nearly 82% effective at preventing severe disease from RSV in newborns during the first 90 days of life. There were about 7,000 participants in the clinical trial.

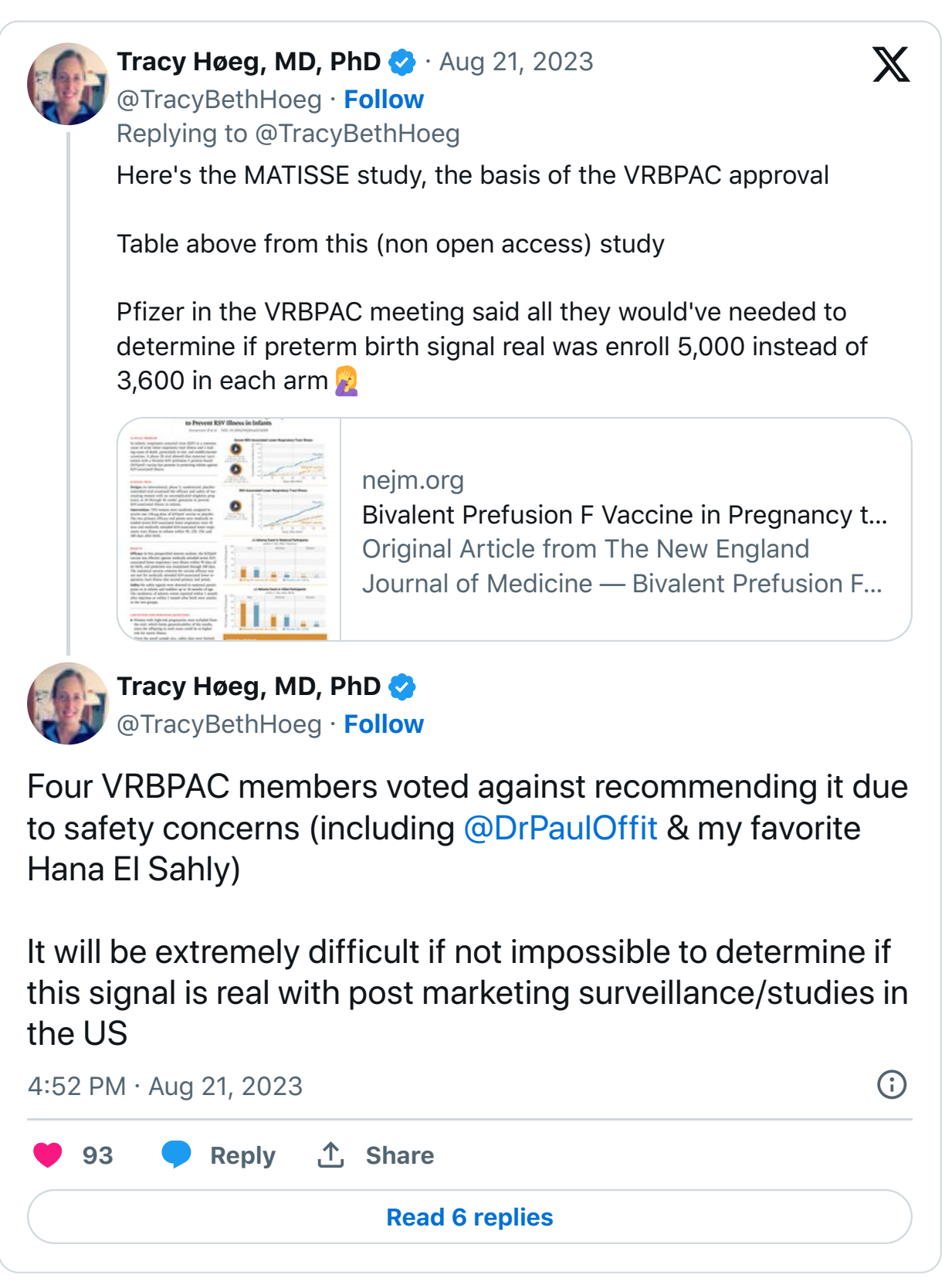
The vaccine was also reported to be about 70% effective during the first six months of the baby's life, CNBC reported.

But experts, including four members of the VRBPAC committee who voted against recommending the vaccine for pregnant women, said they had concerns about the study.

Tracy Høeg, M.D., Ph.D., reported there was a 20% higher rate of preterm birth in the vaccinated group than in the unvaccinated group.

"Most of VRBPAC shrugged off the signal as 'non significant' but study underpowered," she tweeted — meaning there were not enough participants in the study to confirm whether the safety signal was statistically significant.

Høeg shared more details on Twitter:



Tracy Høeg, MD, PhD · Aug 21, 2023
@TracyBethHoeg · Follow
Replying to @TracyBethHoeg
Here's the MATISSE study, the basis of the VRBPAC approval

Table above from this (non open access) study

Pfizer in the VRBPAC meeting said all they would've needed to determine if preterm birth signal real was enroll 5,000 instead of 3,600 in each arm 🤦‍♀️

nejm.org
Bivalent Prefusion F Vaccine in Pregnancy t...
Original Article from The New England Journal of Medicine — Bivalent Prefusion F...

Tracy Høeg, MD, PhD
@TracyBethHoeg · Follow

Four VRBPAC members voted against recommending it due to safety concerns (including @DrPaulOffit & my favorite Hana El Sahly)

It will be extremely difficult if not impossible to determine if this signal is real with post marketing surveillance/studies in the US

4:52 PM · Aug 21, 2023

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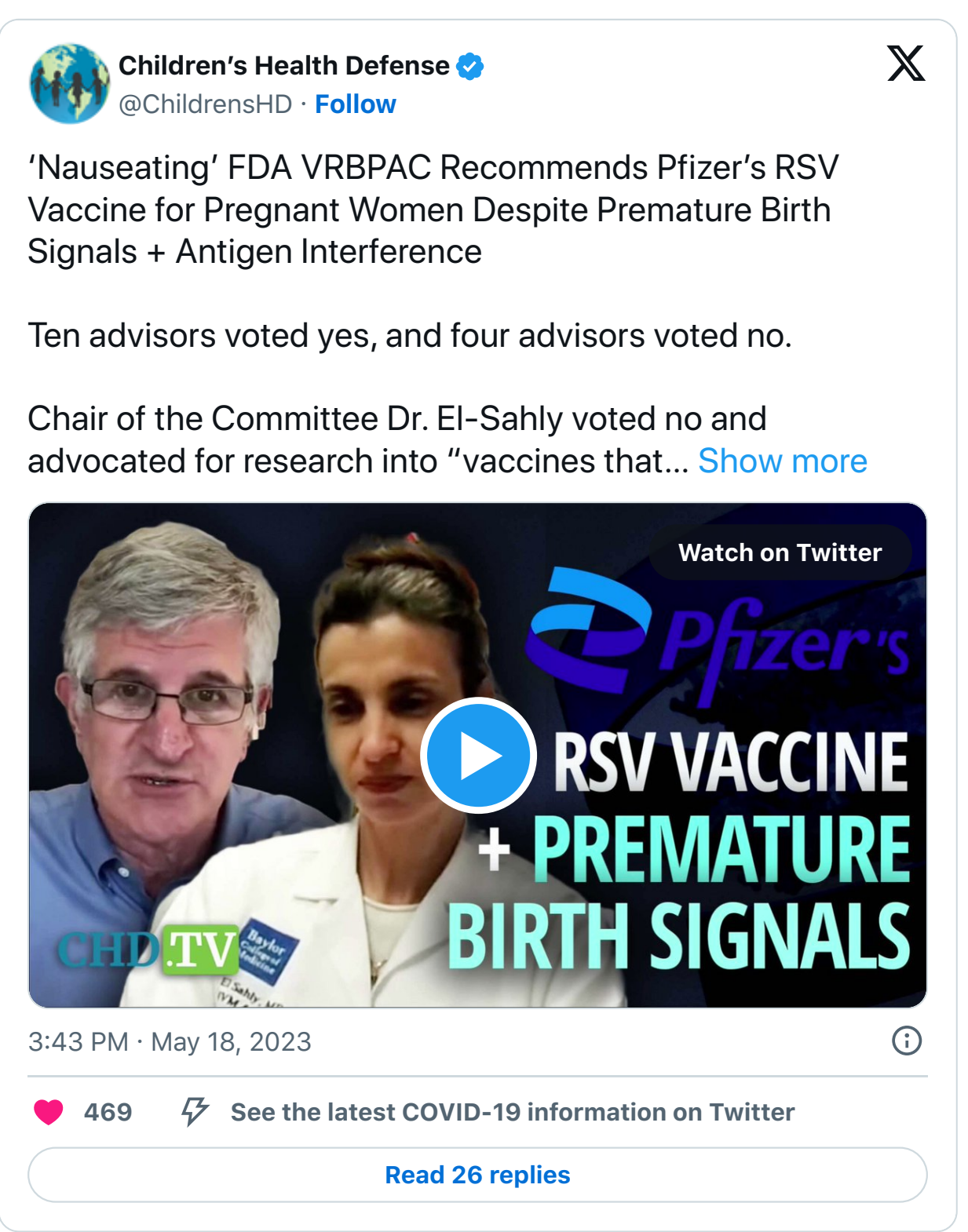
Offit voted against approving the vaccine because of the safety signal.



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@ChildrensHD · Follow

'Nauseating' FDA VRBPAC Recommends Pfizer's RSV Vaccine for Pregnant Women Despite Premature Birth Signals + Antigen Interference

Ten advisors voted yes, and four advisors voted no.

Chair of the Committee Dr. El-Sahly voted no and advocated for research into "vaccines that... Show more

3:43 PM · May 18, 2023

469 See the latest COVID-19 information on Twitter

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The FDA, following Monday's approval, said the available data "are insufficient to establish or exclude a causal relationship between preterm birth" and Pfizer's vaccine, CNBC reported.

It also reported that Pfizer's VP of Vaccine Research and Development Alejandra Gurtman said the difference in premature birth rates was "not statistically significant."

Gurtman noted that most premature births occurred 30 days after vaccination, which she said means "a very close causal relationship between the vaccine and preterm birth couldn't be identified."

"We couldn't find any reason why this really happened," Gurtman said.

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GSK stopped development of the same type of maternal RSV vaccine earlier this year when it detected a similar increase in the number of preterm births among pregnant mothers.

Other commonly reported side effects from Abrysvo included pain at the injection site, headache, muscle pain and nausea.

Pre-eclampsia also occurred in 1.8% of pregnant women who took the drug, relative to 1.4% of women in the placebo group.

The company said it will continue to examine risks in a post-marketing vaccine study, and as part of that, it will create a registry for adverse event reporting.

McCullough wrote on his Substack that this vaccine is more evidence that "Vaccine ideology or hubris appears everywhere! Never had we heard so much about vaccines in our day to day life as laypersons or as healthcare professionals."

He added:

> "Pfizer has aggressively advanced RCTs into the pregnant population with no assurances on long term outcomes. There is no direct benefit to the mothers.
>
> "Furthermore, the sponsors moved the goalposts to make it easier to have a successful trial. We should demand long-term safety, high efficacy … and at least one year of durability, for such a rare and easy-to-treat condition in babies."

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Brenda Baletti, Ph.D.

Brenda Baletti Ph.D. is a reporter for The Defender. She wrote and taught about capitalism and politics for 10 years in the writing program at Duke University. She holds a Ph.D. in human geography from the University of North Carolina at Chapel Hill and a master's from the University of Texas at Austin.

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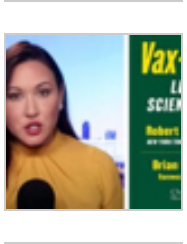

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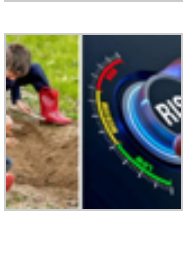

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Bonnie Gillmore
13 days ago
I can't for the life of me understand why any pregnant woman would get a vaccine.
14 0 Reply • Share ›

Grumpy Granny → Bonnie Gillmore
13 days ago
I even avoided aspirin.
6 0 Reply • Share ›

Bonnie Gillmore → Grumpy Granny
12 days ago
Same here
1 0 Reply • Share ›

BraveNewWhirled → Bonnie Gillmore
13 days ago
After watching the behavior of the drug companies, the FDA, hospitals, doctors, and politicians during the last 3.5 years, I can't understand why anyone would trust any of these entities ever again. I don't like feeling that way but I cannot deny what I saw and heard.

Why would a mother give her child to a clinical study? That's pure ignorance.
5 0 Reply • Share ›

QuentonQuale → Bonnie Gillmore
10 days ago
True. They tell pregnant women to avoid drinking alcohol but injecting a combination of chemicals directly into the bloodstream is A-OK. The FDA has just become a rubber stamp for pharma, no longer concerned about anyone's health.
3 0 Reply • Share ›

holisticpoet
13 days ago
The sad thing is that if the FDA recommended it for pregnant woman, you can be sure that it will do harm to the pregnancy, the child, if it makes it full term, and the mother herself. The more educated people are less likely to tolerate being being slaves to the ruling class. Why do you think the borders have been virtually open for so long?
12 0 Reply • Share ›

Darby O'Gill
13 days ago
We have many men and women with evil intentions in positions of authority throughout the world.
9 0 Reply • Share ›

BraveNewWhirled → Darby O'Gill
13 days ago
You're right. Evil and greedy people seek positions of power and influence over other people.
2 0 Reply • Share ›

ABoleynGirl
13 days ago
"RSV generally causes only mild, cold-like symptoms in infants and young children, most of whom get the illness by age 2 and typically don't require medical attention.."
And, I would want a "vaccine" for "mild cold like symptoms", why?
If the vaccine works, give it to those people who are at risk of having a "cold" turn into something more serious.
7 0 Reply • Share ›

QuentonQuale → ABoleynGirl
10 days ago
Like Covid, it's another alleged virus that's never been isolated and has the same vague symptoms shared by all alleged viruses like colds and flus. Another cash cow for vaccine makers. Snake oil in a vial.
1 0 Reply • Share ›

Simons
13 days ago
Be advised: the 21st Century Cures Act of 2016 waives manufacturer's liability for all vaccines recommended by CDC for pregnant women. There is no incentive for manufacturers to thoroughly study the vaccine carefully or to manufacture it to strict safe standards. If you or your baby is injured you can only seek compensation for your injury from the Vaccine Injury Program.
6 0 Reply • Share ›

Leslie Taylor
13 days ago edited
"Pfizer has aggressively advanced RCTs into the pregnant population with no assurances on long term outcomes. There is no direct benefit to the mothers." "Furthermore, the sponsors moved the goalposts to make it easier to have a successful trial." On that note, I had just read this:

Heinz Kohut (1913 - 1981) the eminent Austrian born American psychoanalyst believed that conventional scientific methodology was "experience-distant," removed from actual observation. He proposed an "experience-near" approach in which data could be acquired directly inclusive of empathy and introspection. Empathy is crucial, he maintained, to prevent scientific pursuits from "becoming increasingly isolated from human life." Eliminating empathy from science, he believed, had resulted in a cold, disinterested and rational science that fostered the aims of brutal totalitarian regimes and had led to "some of the most inhuman goals the world has ever known."
5 0 Reply • Share ›

Steven Smith
12 days ago
RSV is a "narrative" to cover for childhood vaccine damage and autoimmune diseases caused by the vaccines. No RSV "virus" has ever been identified and proven to exist. We have been scammed on all of the "vaccines"
4 0 Reply • Share ›

QuentonQuale → Steven Smith
10 days ago
Amen brother.
0 0 Reply • Share ›

Dee
13 days ago
They promote fear to get the fearful to vaccinate. These fearful people don't even look at the stats, at how rare & inconsequential the actual illness is, if one gets it, they just go for the jab instead, no critical thinking, no self preservation or safety concerns for the baby. The jabs are WAY worse than the illness. I guess it's just survival of the fittest (mentally). The poor babies don't get a say.
3 0 Reply • Share ›

stella
13 days ago
Those death estimates are a lie. They are scare tactics to get people to take the shot just like they did for the covid shot. Follow the money. Dr. McCullough said it is easily treated with nebulizers. They are always working on the pregnant women, I guess the scare more easily. They need to be more scared to get the shot than to not get it. Money making scare tactics.
3 0 Reply • Share ›

Henry Longstop
12 days ago
I suppose we can at least applaud Dr Offit for finally growing a pair of testicles and resisting rubber stamping the Pfizer RSV vaccine by voting against approval on safety grounds.
I would be more unequivocal if it wasn't for the fact that Dr Offit also holds a patent for his own RSV vaccine which could potentially lose market share if the Pfizer shot is successful.
I don't want to think ill of Dr Offit but it looks like there is a risk his decision might be based more on commercial rather than medical or ethical considerations.
2 0 Reply • Share ›

Ricky Ricardo
8 days ago edited
Allow me to sum up our current situation in a nutshell. Up to this point, nothing that all the good people working to end this insanity, have done, has slowed these evil minions down at all! They are rolling out all of their nefarious agendas at breakneck speed. I hope you're all prepared for The Great Reset and the One World Government! Avoid the "Fall Shots" like the plague! My **immune system** is all the "help" I need to "Stay Safe"!
1 0 Reply • Share ›

Gary Brown
12 days ago edited
August 23, 2023 COVID mRNA and Pregnancy: Skyrocketing Deaths of Vaccinated Pregnant Women. Dr. William Makis

CDC: Maternal Mortality Is Up Over 50% After COVID-19 Vaccines Rolled Out in December 2020. Here are 50 deaths of COVID-19 vaccinated pregnant women and new mothers: Aug.15, 2023 – Scottsburg, IN – 34 year old Devonnia Tscheulin, a Paramedic and Deputy Chief for Scott County EMS, died from complications during delivery of her third child (photos above).

https://www.globalresearch....
1 0 Reply • Share ›

Paul Hastilow
13 days ago
Dear Defender , in All Honesty, the more you report on these "Idiotic and Criminal topics"
The more Exposure these Agencies receive…….! It's Uncalled for… Treat them with Disdain…!
Fine to Comment on it, but don't Glorify it, as if They Know what's best for Us.!
Which they don't ….and Never Will.
Rather Ridicule as Their "MissInformation"……that's been going on for 3 yrs Now.
1 0 Reply • Share ›

r2bzjudge
6 days ago
"In its statement to investors, however, Pfizer was enthusiastic about the prospect of the vaccine."

I am enthusiastic about rejecting the RSV vaccine for my personal use. Pfizer has no liability if i am injured by it, so i will protect myself from their product by not taking it.

"Offit voted against approving the vaccine because of the safety signal."

The FDA should not be ignoring the safety signals. The CDC should not be hiding safety signals, as they did with the Covid shots.
0 0 Reply • Share ›

Diane Kane
12 days ago
These and many other vaccines, in addition to viruses themselves, are mutating the DHCR7 enzyme. It is the 7-dehydrocholesterol gene which encodes for the 7-dehydrocholesterol enzyme which is a necessary co-factor in the final step of cholesterol biosynthesis. With the disruption or prevention of cholesterol synthesis, deformation occurs. These are cell and tissue generating pathways and when either genetically or epigenetically dysregulated they will prevent cholesterol efflux from cells which will cause anatomical deformation. Fetuses will fail in the face of severe DHCR7 mutations; otherwise, infants can be born with variable levels of syndromic illnesses like Smith Lemli Opitz, Timothy, or Downs Syndromes if they survive; or lesser anatomical infractions which lead to hypersensitivities and structural frailties. People like me with Asperger's Syndrome have been proven to have DHCR7 mutations.
0 0 Reply • Share ›

BoredHousewife
12 days ago
And a control group of breast feeding mothers had what level of efficacy?
0 0 Reply • Share ›

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